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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,227

12/19/2005

Werner Mederski

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EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

08/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,227	Applicant(s) MEDERSKI ET AL.	
	Examiner Shawquia Young	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 are currently pending in the instant application.

I. *Priority*

The instant application is a 371 of PCT/EP04/05717, filed on May 27, 2004 and claims benefit of Foreign Application Germany 103-27428.6, filed on June 18, 2003 and Germany 103-2957.0, filed on July 1, 2003.

Acknowledgment is made of applicant's claim for foreign priority based on the applications filed in Germany on June 18, 2003 and July 1, 2003. It is noted, however, that applicant has not filed a certified copy of the above Foreign applications as required by 35 U.S.C. 119(b).

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on December 19, 2005 is in partial compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been partially considered by the examiner.

III. *Restriction/Election*

A. *Election: Applicant's Response*

Applicants' election with traverse of Group VIII drawn to compounds of formula I wherein: R is as defined in Claim excluding Het or Het-alkyl; R¹ is as defined in claim 1 excluding Het or Het-alkyl; R² is H, Hal or A; R³ is morpholinyl; X is aryl or arylalkyl; A is as defined in Claim 1; m is 1, 2, 3, 4, 5 or 6; and n is 0, 1, 2, 3, 4, 5 or 6 in

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the reply filed on July 19, 2007 is acknowledged. The traversal is on the ground(s):1) all claims contain a special technical feature, i.e. formula I.

All of the Applicants' arguments have been considered and have been found persuasive. The Examiner has withdrawn the restriction requirement because Applicants' special technical feature does provide a contribution over the art.

IV. Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

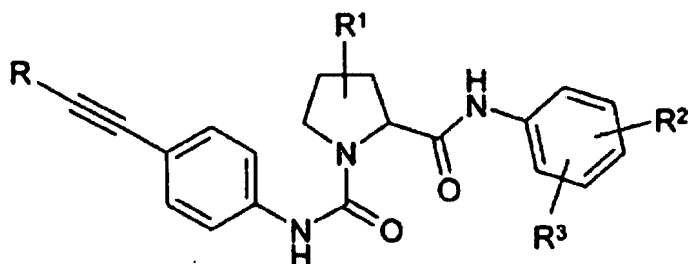
Claims 1, 2, and 13-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 9-16 of copending US application 10/594,024. This is a provisional obviousness-type double patenting

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rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Applicants' elected subject matter is a compound of formula I



, wherein R is H, X, A, X-CO- or A-

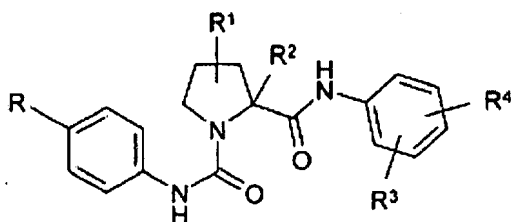
CO-; R¹ is H, =O, Hal, X, A, OH, OA, A-COO-, A-CONH-, A-CONA-, N₃, NH₂, NO₂, CN, COOH, COOA, CONH₂, CON(A)₂, O-allyl, O-propargyl, O-benzyl, =N-OH, =N-OA, OCH₂CH(OH)CH₂OH, A-O-CO-(CH₂)_m-O-, -O(CH₂)_mCOOH or -O(CH₂)_mOA; R² is H, Hal or A; R³ is a monocyclic saturated, unsaturated or aromatic heterocyclic radical having from 1 to 4 N, O and/or S atoms, which may be unsubstituted or mono-, di- or trisubstituted by Hal, A, OA, CN, (CH₂)_nOH, NR⁴R⁵, =NH, =N-OH, =N-OA, COOA and/or carbonyl oxygen (=O) or CONR⁴R⁵; R² and R³ together are alternatively -CH=CH-NH or -CH₂-CH₂-NH, where one H atom may be replaced by A-CO- or A-O-CO; R⁴ and R⁵ independently of one another, are H or A; R⁴ and R⁵ together are alternatively an alkylene chain having 3, 4 or 5 carbon atoms, which may also be substituted by A, Hal, OA and/or carbonyl oxygen (=CO); X is aryl, arylalkyl, Het or Het-alkyl; A is unbranched, branched or cyclic alkyl having 1-10 carbons atoms, in which, in addition, 1-7 H atoms may be replaced by F and/or chlorine; Hal is F, Cl, Br or I; m is 1,2, 3, 4,5 or 6; n is 0, 1,

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2, 3, 4, 5 or 6 and pharmaceutically usable derivatives, salts, solvates and stereoisomers thereof, including mixtures thereof in all ratios.

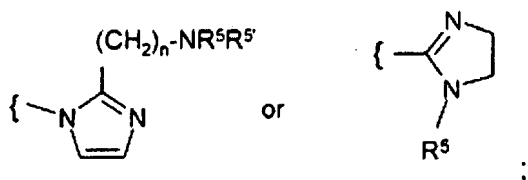
Determining the Scope and Content of the Copending Application

Claim 1 of the copending application claims a compound of the formula



, wherein R is Hal, $-\text{C}\equiv\text{C}-\text{H}$, $-\text{C}\equiv\text{C}-\text{A}$ or OA ; R^1

is H, =O, Hal, A, OH, OA, A-COO-, Ph-(CH₂)_n-COO-, cycloalkyl-(CH₂)_n-COO-, A-CONH-, A-CONA-, Ph-CONA-, N₃, NH₂, NO₂, CN, COOH, COOA, CONH₂, CONHA, CON(A)₂, O-allyl, O-propargyl, O-benzyl, =N-OH, =N-OA, =CF₂; R^2 is H or A; R^3 denotes H, Hal or A; R^4 is C₆H₄-(CH₂)_n-NR⁵R^{5'}, -C(=NR⁵)NR⁵R^{5'},



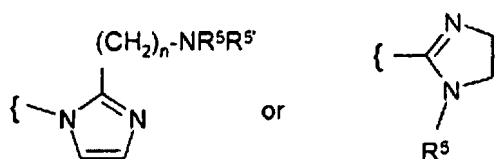
R^5 and $\text{R}^{5'}$ each independently of one another, denote H or A; n is 0, 1, 2, or 3 and pharmaceutically usable derivatives, salts, solvates and stereoisomers thereof, including mixtures thereof in all ratios.

Ascertaining the Differences Between the Instant Application and the Copending Application

The claims of the instant application are drawn to a broader compound genus than the claims of the copending application, which encompass the elected

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subject matter of the copending application. In the instant application, R^3 is a monocyclic saturated, unsaturated or aromatic heterocyclic radical having from 1 to 4 N, O and/or S atoms, which may be unsubstituted or substituted as defined in claim 1 whereas the copending application R^4 is R^4 is $C_6H_4-(CH_2)_n-NR^5R^{5'}$, $-C(=NR^5)NR^5R^{5'}$,



Finding Prima Facie Obviousness

As mentioned above, the genus compound of the instant application encompasses the narrower genus compound in the copending application's claims 1, 2 and 9-16. The scope of the compounds in the claims 1, 2 and 9-16 of the copending application and the scope of the elected subject matter of claims 1, 2, and 13-20 of the instant application overlap and include subject matter of the copending application in the claims of the instant application. Therefore, one of ordinary skill in the art would be motivated to prepare and claim the scope of the compounds in the instant application since the scope already in the copending application is encompassed by the scope of the elected subject matter in the instant claims 1, 2, and 13-20. As a result, the claims are rejected under obviousness-type double patenting.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (I) does not reasonably provide enablement for pharmaceutically usable derivatives of a compound of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

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The nature of the invention is a compound of formula (I) or pharmaceutically usable derivatives, salts, solvates, and stereoisomers, prodrug thereof.

The state of the prior art and the predictability or lack thereof in the art

It is the state of the prior art that the term "derivative" found in the claims is defined as a compound, usually organic obtained from another compound by a simple chemical process or an organic compound containing a structural radical similar to that from which it is derived (Hackh's chemical dictionary, 1972). Since the compound as claimed are reported to be novel, there should not be any prior art that disclose such compounds or preparation of such compounds.

The existence of these obstacles establishes that one of ordinary skill in the art would not know what chemical structures are encompassed by the term "pharmaceutically usable derivatives". In the instant case, the specification does not provide guidance as to how one skilled in the art would ascertain what would be considered an appropriate substitution to make for a "pharmaceutically usable derivatives".

The amount of direction or guidance present and the presence or absence of working examples

The specification does not provide working examples in which pharmaceutically usable derivatives are synthesized. It does not provide direction for the preparation of any pharmaceutically usable derivative of the compound of formula I. Since the

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chemical moieties encompassed by these terms are variable in reactivity, it cannot be said with absolute certainty such compound can be prepared through the same route as compounds of formula I.

The breadth of the claims

The breadth of the claims is broader than the disclosure, specifically, the instant claims include compounds of formula I and "pharmaceutically usable derivatives." Thus, multiple derivatives of the compounds of formula I having various functional groups and chemical reactivity are encompassed by the instant claims. However, the specification only provides evidence for compounds of formula I and does not provide examples of the pharmaceutically usable derivatives.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with both similar and different structural radicals without any direction as to what structural radical is needed and how different the pharmaceutically usable derivative can be from a compound of formula (I).

The level of skill in the art is high without showing or guidance as to how to make pharmaceutically usable derivatives of a compound of formula (I) it would require undue experimentation to figure out the starting materials, solvents, temperatures and reaction times that would provide pharmaceutically usable derivatives of the above compounds.

In consideration of each of the 8 factors, it is apparent that undue

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experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

To overcome this objection, Applicant should submit an amendment deleting the phrase "pharmaceutically usable derivatives".

(2) Claims 14, 15, 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,

6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case,

The nature of the invention

The nature of the invention is a compound of formula I as inhibitors of coagulation Xa and VIIa, the use of compounds of formula I for the preparation of a medicament for the treatment of thrombosis, myocardial infarction, arteriosclerosis, inflammation, apoplexia, angina pectoris, restenosis after angioplasty, claudicatio intermittens, migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In *re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is

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the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of any condition considered, whether or not the condition is effected by the activity of the products of the claimed invention would make a difference.

Applicants claims are drawn to a use of compounds of formula I for the preparation of a medicament for the treatment of thrombosis, myocardial infarction, arteriosclerosis, inflammation, apoplexia, angina pectoris, restenosis after angioplasty, claudicatio intermittens, migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis.

Applicants' claims, for example, include the treatment of any cancer. The state of the prior art is that cancer therapy remains highly unpredictable. Tumors is an abnormal growth of body tissue and can be cancerous or non-cancerous. Therefore, tumors, tumor diseases and/or tumor metastasis all relate to cancer. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. Cancer is a disease characterized by a population of cells that grow and divide without respect to normal limits, invade and destroy adjacent tissues, and may spread to distant anatomic sites through a process called metastasis ([URL:http://en.wikipedia.org/wiki/ Cancer](http://en.wikipedia.org/wiki/Cancer)>). Most cancers are named for where they start. For example, lung cancer starts in the lung, and breast cancer starts in the breast. Symptoms and treatment depend on the cancer type and how advanced it is (([URL:http://www.nlm.nih.gov/medlineplus/print/ cancer.html](http://www.nlm.nih.gov/medlineplus/print/cancer.html))>). It is

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known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al. page 531). Treatment may include surgery, radiation, chemotherapy, immunotherapy, monoclonal antibody therapy, etc.

Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them. It is also known in the prior art (Lala et al. page 91) that the role of NO in tumor biology remains incompletely understood with both the promotion and inhibition of NO mentioned for the treatment of tumor progression and only certain human cancers may be treated by selected NO-blocking drugs. These example shows that there are different cellular mechanisms, the unpredictability in the art and the different treatment protocols. Because "cancer" refers to a class of diseases, it is unlikely that there will ever be a single "cure or treatment for cancer".

The amount of direction present and the presence or absence of working examples

The only direction or guidance present in the instant specification is minimal. The specification only gives a list of conditions considered to be treated by the compounds of formula I. There are no working examples present for the treatment of any specific disease or disorder.

Test assays and procedure are provided in the specification at page 34 for inhibitory activity of coagulation factor Xa and coagulation factor VIIa. It is inconceivable as to how the claimed compounds can treat the extremely difficult diseases embraced by the instant claims.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The breadth of the claims

The breadth of the claims is a compound of formula I as inhibitors of coagulation Xa and VIIa, the use of compounds of formula I for the preparation of a medicament for the treatment of thrombosis, myocardial infarction, arteriosclerosis, inflammation, apoplexia, angina pectoris, restenosis after angioplasty, claudicatio intermittens, migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases would be benefited by the activity of the claimed compounds of formula I and would furthermore then have to determine which of the claimed compounds in the instant invention would provide treatment of the

diseases.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* or *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The specification fails to provide sufficient support of the broad use of the claimed compounds of the invention for the treatment of thrombosis, myocardial infarction, arteriosclerosis, inflammation, apoplexia, angina pectoris, restenosis after angioplasty, claudicatio intermittens, migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis. As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated by what compounds of the invention in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the

compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome, for example, by deleting the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- (1) Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-20 are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claims 1-20 are drawn to "a compound of the formula (I) and pharmaceutically usable derivatives, salts, solvates and stereoisomers thereof." However, the "pharmaceutically usable derivative" of the compounds of Claims 1-20 are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claims are indefinite. Applicants are suggested to delete the phrase "pharmaceutically usable derivatives".
- (2) Claims 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps involve the synthetic steps of how to prepare the pharmaceutical composition of claims 18 and 20.
- (3) Claims 17, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as

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being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17, 19 and 20 recites the limitation "at least one further medicament active ingredient". On page 6 of the specification, it is stated that the compound can be employed with other thrombolytically active compounds or blood platelet glycoprotein receptor (IIb/IIIa) antagonists, but the specification does not state if these compounds are what is considered "one further medicament active ingredient" and fails to defined the term or teach exactly what is meant by "one further medicament active ingredient". Thus, "at least one further medicament active ingredient" is not defined so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

(4) Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 contains the phrases "chloroformate derivative" and "carbamate derivative" in the step (a) of the process claim. However, "chloroformate derivative" and "carbamate derivative" are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 9-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The phrase "Use of a compound..." is written in improper format because a "use" can only be properly claimed as a process or method. It is suggested that applicant amend the claims by rewriting the claims as a process or method, i.e. "a method of preparing..."

V. Objections

Claim Objections

Claims 14 and 15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. A compound's intended use does not further limit the claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

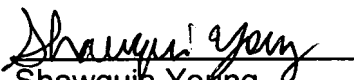
VI. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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